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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,296	01/24/2002	R. Eric Montgomery	P1083US01	9773

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EXAMINER	
JAGOE, DONNA A	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/056,296	MONTGOMERY, R. ERIC	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7,11,12,16-35,37-39,41-43,45,46 and 55-63* is/are pending in the application.

4a) Of the above claim(s) *61-63* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,11,12,16-35,37-39,41-43,45,46 and 55-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 24, 2007 has been entered.

Newly submitted claims 61-63 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the concept of a "curable composition" is distinct from the claims drawn to an oral care composition and does not require all the limitations of the product originally presented, therefore all claims directed to that newly added invention are withdrawn from consideration.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 61-63 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1-5, 7, 11, 12, 16-35, 37-39, 41-43, 45, 46 and 55-60 are pending in this application.

Applicants' arguments filed October 24, 2007 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 7, 11, 12, 16-35, 37-39, 41-43, 45, 46 and 55-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Show Denko KK JP 62096408 in view of Pera U.S. Patent No. 4,775,525. and Parran et al. U.S. Patent No. 4684518.

The claims are drawn to a composition comprising ascorbyl-2-phosphate or a sodium or potassium salt thereof and further comprising calcium ions wherein the

composition is mixed with an orally acceptable carrier, and further comprising a calcium chelating agent, a pyrophosphate, tripolyphosphate or polyphosphate tartar control agent, a water soluble fluid, water soluble solid, humectant, thickener, surfactant, sweetener, flavorant, colorant, abrasive, stabilizer, fluoride containing compound, anticaries agent, antimicrobial agent, essential oil and a desensitizing agent.

Showa Denko KK teach ascorbic acid phosphoric acid ester or it's salt (e.g. Na^+, K^+, Ca^{++} or Mg^+ salt) in an oral composition to be used for alveolar pyorrhea, cleaning teeth, removing bad breath and washing the teeth. It is in compositions such as toothpaste, chewing gum and troches. Working example I teaches calcium diphosphate dihydrate (source of calcium/abrasive), sodium carboxymethylcellulose and carrageenan (thickeners), glycerin (water soluble liquid), sorbital (water soluble solid), fragrance (flavor), preservative (antimicrobial), sodium saccharin (sweetener), sodium lauryl sulfate (surfactant), and ascorbic acid magnesium phosphate.

Showa Denko does not teach the desensitizing agents of claims 40-44, it does not teach the non water-soluble solid and liquid and it does not teach the pyrophosphate, tripolyphosphate or polyphosphate tartar control agent.

Pera (4,775,525) teaches strontium as a desensitizing agent for the teeth (column 5, lines 27-43).

It would have been made obvious to one of ordinary skill in art at the time it was made to incorporate desensitizing agents and vegetable oils and wax. Such a modification would have been motivated by the reasoned expectation of producing a dentifrice composition which is effective in comprehensively cleaning teeth and

desensitizing teeth of individuals that have become sensitized. Strontium is a well-known desensitizer, which is known and used in dentifrices as evidenced by the teachings of Pera (4,775,525). Vegetable oil would aid in mixing the dentifrice composition and the wax would effectively coat the teeth and add shine to the teeth.

Parran et al. teach oral compositions containing pyrophosphate salts which provide an anticalculus (aka tartar) benefit (see abstract) and teach the pyrophosphates salts useful in the invention in an amount of about 1.5% (column 2, lines 28-52) which is encompassed by the claimed 1% to about 4%.

It would have been made obvious to one of ordinary skill in art at the time it was made to incorporate the instantly recited tartar control agents. Such a modification would have been motivated by the reasoned expectation of producing a dentifrice composition, which is effective in comprehensively cleaning teeth and removing tartar. As stated in Parran et al., the pyrophosphate salts provide an anticalculus (tartar control) benefit in dentifrices (see abstract).

Applicant claims a pH of the composition from about 5.5 to about 10.0 now in independent claim 1. However, if applicant wishes to rely on provisional application number 60/263884 ,for a priority date of 1/24/01, the only pH present in the priority document is a teaching of a pH of 8.86 in one specific formulation. There is no recitation of a pH of from about 5.5 to about 10 .

See http://pubs.acs.org/hotartcl/chemtech/95/dec/dec.html December 1995 wherein it is recited that Sodium fluoride, sodium monofluorophosphate, and stannous fluoride are the most common fluoride sources used in toothpaste. Great care must be

taken in the formulation of these agents so that their anticaries activity is not reduced by other dentifrice ingredients, such as the abrasive system. For example, whereas sodium monofluorophosphate is compatible with both silica and dicalcium phosphate dihydrate abrasives, sodium fluoride is most compatible with the silica abrasive at neutral pH values. Thus it would have been obvious to employ a pH of 5.5 to 10 since this range encompasses neutral pH's and this would be most compatible for formulations with fluoride.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35, 39, 43 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely

exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, **claim 35** recites the broad recitation "wherein the anticaries agent comprises from about 0.1% to about 4% by weight of the composition", and the claim also recites "or from about 0.2% by weight to about 0.8%" which is the narrower statement of the range/limitation.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, **claim 39** recites the broad recitation "wherein the antimicrobial agent comprises from about 0.01% to about 2% by weight of the composition", and the claim also recites "or from about 0.1% to

about 1% by weight of the composition" which is the narrower statement of the range/limitation.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, **claim 43** recites the broad recitation "wherein the desensitizing agent comprises potassium nitrate in an amount of from about 3% to about 6% by weight of the composition", and the claim also recites "or in an amount of about 5% by weight of the composition" which is the narrower statement of the range/limitation.

Response to Arguments

Applicant asserts that there is no motivation to combine the prior art. This is not persuasive because the strongest rationale for combining references is a recognition,

expressly or implicitly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. See In re Sernaker 17 USPQ 1, 5-6 (Fed. Cir. 1983) and MPEP 2144. Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Regarding applicant's argument that the prior art teaches away from the instant invention, the Examiner directs Applicant's attention to *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments.

Regarding the pH of the composition, as stated above, http://pubs.acs.org/hotartcl/chemtech/95/dec/dec.html December 1995 recites that Sodium fluoride, sodium monofluorophosphate, and stannous fluoride are the most common fluoride sources used in toothpaste. Great care must be taken in the formulation of these agents so that their anticaries activity is not reduced by other

dentifrice ingredients, such as the abrasive system. For example, whereas sodium monofluorophosphate is compatible with both silica and dicalcium phosphate dihydrate abrasives, sodium fluoride is most compatible with the silica abrasive at neutral pH values. Thus it would have been obvious to employ a pH of 5.5 to 10 since this range encompasses neutral pH's and this would be most compatible for formulations with fluoride.

Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna Jagoe
Patent Examiner
Art Unit 1614

January 6, 2008